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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-364]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: DEA is announcing two new DEA-approved certification processes for providers of Electronic Prescriptions for Controlled Substances (EPCS) applications. Certifying organizations with a certification process approved by DEA pursuant to 21 Code of Federal Regulations (CFR) 1311.300(e) are posted on DEA's website upon approval.

FOR FURTHER INFORMATION, CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

The Drug Enforcement Administration (DEA) implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the

Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended, and referred to as the Controlled Substances Act (CSA).¹ DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

The CSA and DEA's implementing regulations establish the legal requirements for possessing and dispensing controlled substances, including the issuance of a prescription for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). A prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been properly dispensed. The maintenance of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress.

Electronic Prescriptions for Controlled Substances (EPCS)

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the

¹ The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA amended its regulations to provide practitioners with the option of issuing electronic prescriptions for controlled substances in lieu of paper prescriptions. Efforts to develop EPCS capabilities have been underway for a number of years. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236-16319, and became effective on June 1, 2010.

Update

Certifying organizations with a certification process approved by DEA pursuant to 21 CFR 1311.300(e).

As noted above, the Interim Final Rule provides that, as an alternative to the audit requirements of 21 CFR 1311.300 (a) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR Part 1311 by a certifying organization whose certification process has been approved by DEA. The preamble to the Interim Final Rule further indicated that, once a qualified certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such information will be posted on DEA's website. 75 FR 16243 (March 31, 2010). On January 18, 2013, DEA approved the certification processes developed by Global Sage Group, LLC, and by iBeta, LLC. iBeta's certification process was previously approved by DEA but only with regard to the certification of the application's biometrics subsystem, including its interfaces. 77 FR 45688 (August 1, 2012). This approval for iBeta's certification process is expanded to include the entire

certification process. Relevant information has been posted on DEA's website at <http://www.DEAdiversion.usdoj.gov>.

Dated: March 20, 2013

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

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